



Dkt.61009-A/JPW/MAF/AJD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: William C. Olson and Paul J. Maddon
U.S. Serial No.: 10/681,879
Filed: October 9, 2003
For: COMPOSITIONS AND METHODS FOR INHIBITION OF
HIV-1 INFECTION

1185 Avenue of the Americas
New York, New York 10036
October 29, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following references which are listed on the attached Form PTO-1449 (**Exhibit A**):

1. U.S. Patent No. 5,464,733-A, issued November 7, 1995 to Bolognesi et al.;
2. U.S. Patent No. 5,603,933-A, issued February 18, 1997 to Dwyer, IV et al.;
3. U.S. Patent No. 5,668,149-A, issued September 16, 1997 to Oroszlan et al.;
4. U.S. Patent No. 5,817,767-A, issued October 6, 1998 to Allaway et al.;
5. PCT International Publication No. WO 92/01451-A1, published February 6, 1992 (Vitetta ES and Uhr J);
6. Allaway GP et al. (1995) Expression and characterization of

CD4-IgG2, a novel heterotetramer which neutralizes primary HIV-1 isolates. AIDS Res Hum Retroviruses 11: 533-539;

7. Allaway GP et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. AIDS Res Hum Retroviruses 9: 581-587;
8. Allaway GP et al. (1993) Synergistic inhibition of HIV-1 envelope-mediated cell fusion by CD4-based molecules in combination with antibodies to gp120 or gp41. J Cell Biochem 17E: 25, see abstract;
9. Arthos J et al. (1989) Identification of the residues in human CD4 critical for the binding of HIV. Cell 57: 469-481;
10. Burkly L et al. (1995) Synergistic inhibition of human immunodeficiency virus type 1 envelope glycoprotein-mediated cell fusion and infection by an antibody to CD4 domain 2 in combination with anti-gp120 antibodies. J Virol 69: 4267-4273;
11. Burton DR et al. (1994) Efficient neutralization of primary isolates of HIV-1 by a recombinant human monoclonal antibody. Science 266: 1024-1027;
12. Capon DJ et al. (1989) Designing CD4 immunoadhesins for AIDS therapy. Nature 337: 525-531;
13. Chan DC et al. (1998) Evidence that a prominent cavity in the coiled coil of HIV type 1 gp41 is an attractive drug target. Proc Natl Acad Sci USA 95: 15613-15617;
14. Clapham PR et al. (1989) Soluble CD4 blocks the infectivity

- of diverse strains of HIV and SIV for T cells and monocytes but not for brain and muscle cells. Nature 337: 368-370;
15. Cushman M et al. (1991) Preparation and anti-HIV activities of aurintricarboxylic acid fractions and analogues: direct correlation of antiviral potency with molecular weight. J Med Chem 34: 329-337;
 16. Deen KC et al. (1988) A soluble form of CD4 (T4) protein inhibits AIDS virus infection. Nature 331: 82-84;
 17. Eckert DM et al. (1999) Inhibiting HIV-1 entry: Discovery of D-peptide inhibitors that target the gp41 coiled-coil pocket. Cell 99: 103-115;
 18. Ferrer M et al. (1999) Selection of gp41-mediated HIV-1 cell entry inhibitors from biased combinatorial libraries of non-natural binding elements. Nature Struct Biol 6: 953-959;
 19. Fouts TR et al. (1997) Neutralization of the human immunodeficiency virus type 1 primary isolate JR-FL by human monoclonal antibodies correlates with antibody binding to the oligomeric form of the envelope glycoprotein complex. J Virol 71: 2779-2785;
 20. Gait MJ et al. (1995) Progress in anti-HIV structure-based drug design. Trends Biotech 13: 430-437;
 21. Gauduin M-C et al. (1996) Effective ex vivo neutralization of plasma HIV-1 by recombinant immunoglobulin molecules. J Virol 70: 2586-2592;
 22. Jacobson J et al. (1999) Results of a phase I trial of single-dose PRO 542, a novel inhibitor of HIV entry.

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23. Ji H et al. (1999) Inhibition of human immunodeficiency virus type 1 infectivity by the gp41 core: role of a conserved hydrophobic cavity in membrane fusion. J Virol 73: 8578-8586;
24. Jiang S et al. (1993) HIV-1 inhibition by a peptide. Nature 365: 113;
25. Kirby JM et al. (1998) Potent suppression of HIV-1 replication in humans by T-20, a peptide inhibitor of gp41-mediated virus entry", Nature Med 4: 1302-1307;
26. Laal S et al. (1994) Synergistic neutralization of human immunodeficiency virus type 1 by combinations of human monoclonal antibodies. J Virol 68: 4001-4008;
27. LaCasse RA et al. (1999) Fusion-competent vaccines: broad neutralization of primary isolates of HIV. Science 283: 357-362;
28. Li A et al. (1997) Synergistic neutralization of a chimeric SIV/HIV type 1 virus with combinations of human anti-HIV type 1 envelope monoclonal antibodies or hyperimmune globulins. AIDS Res Hum Retroviruses 13: 647-656;
29. Li A et al. (1998) Synergistic neutralization of simian-human immunodeficiency virus SHIV-vpu+ by triple and quadruple combinations of human monoclonal antibodies and high-titer anti-human immunodeficiency virus type 1 immunoglobulins. J Virol 72: 3235-3240;
30. Litwin V et al. (1996) Human immunodeficiency virus type 1

membrane fusion mediated by a laboratory-adapted strain and a primary isolate analyzed by resonance energy transfer. J Virol 70: 6437-6441;

31. Markosyan RM et al. (2002) The mechanism of inhibition of HIV-1 Env-mediated cell-cell fusion by recombinant cores of gp41 ectodomain. Virology 302: 174-184;
32. Mohan P et al. (1992) Sulfonic acid polymers as a new class of human immunodeficiency virus inhibitors. Antiviral Res 18: 139-150;
33. Nagashima KA et al. (2001) Human immunodeficiency virus type 1 entry inhibitors PRO 542 and T-20 are potently synergistic in blocking virus-cell and cell-cell fusion. J Infect Dis 183: 1121-1125;
34. Olson WC et al. (1999) Differential inhibition of human immunodeficiency virus type 1 fusion, gp120 binding, and CC-chemokine activity by monoclonal antibodies to CCR5. J Virol 73: 4145-4155;
35. Posner MR et al. (1993) Neutralization of HIV-1 by F105, a human monoclonal antibody to the CD4 binding site of gp120. J Acq Immune Defic Synd 6: 7-14;
36. Schols D et al. (1990) Dextran sulfate and other polyanionic anti-HIV compounds specifically interact with the viral gp120 glycoprotein expressed by T-cells persistently infected with HIV-1. Virology 175: 556-561;
37. Schols D et al. (1991) Selective inhibitory activity of polyhydroxycarboxylates derived from phenolic compounds against human immunodeficiency virus replication. J Acq Immune Defic Synd 4: 677-685;

38. Thali M et al. (1992) Cooperativity of neutralizing antibodies directed against the V3 and CD4 binding regions of the human immunodeficiency virus gp120 envelope glycoprotein. J Acq Immune Defic Synd 5: 591-599;
39. Tilley SA et al. (1992) Synergistic neutralization of HIV-1 by human monoclonal antibodies against the V3 loop and the CD4-binding site of gp120. AIDS Res Hum Retroviruses 8: 461-467;
40. Trkola A et al. (1998) Neutralization sensitivity of human immunodeficiency virus type 1 primary isolates to antibodies and CD4-based reagents is independent of coreceptor usage. J Virol 72: 1876-1885;
41. Vijn-Varrier S et al. (1996) Synergistic neutralization of human immunodeficiency virus type 1 by a chimpanzee monoclonal antibody against the V2 domain of gp120 in combination with monoclonal antibodies against the V3 loop and the CD4- binding site. J Virol 70:4466-4473;
42. Vita C et al. (1999) Rational engineering of a miniprotein that reproduces the core of the CD4 site interacting with HIV-1 envelope glycoprotein. Proc Natl Acad Sci USA 96: 13091-13096;
43. Wild C et al. (1993) A synthetic peptide from HIV-1 gp41 is a potent inhibitor of virus- mediated cell-cell fusion. AIDS Res Hum Retroviruses 9: 1051-1053;
44. Wild C et al. (1995) The inhibitory activity of an HIV type 1 peptide correlates with its ability to interact with a leucine zipper structure. AIDS Res Hum Retroviruses 11: 323-325;

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Page 7

45. Wild C et al. (1992) A synthetic peptide inhibitor of human immunodeficiency virus replication: correlation between solution structure and viral inhibition. Proc Natl Acad Sci USA 89: 10537-10541; and
46. Wild C et al. (1994) Peptides corresponding to a predictive alpha-helical domain of human immunodeficiency virus type 1 gp41 are potent inhibitors of virus infection. Proc Natl Acad Sci USA 91: 9770-9774.

The Examiner is respectfully requested to make these references of record in the present application by initialing and dating the enclosed Form PTO 1449, and returning a copy of the executed form to applicants' representatives with the next Communication concerning this application.

The subject application is a continuation of and claims the priority of U.S. Serial No. 09/493,346, filed January 28, 2000. The above listed references 1-5 and 20 were previously cited by the U.S. Patent and Trademark Office in an Office Action issued on May 17, 2001 in connection with U.S. Serial No. 09/493,346. The above listed references 6, 7, 9-16, 19, 21-24, 26-30, 32 and 34-46 were submitted to the United States Patent and Trademark Office in an Information Disclosure Statement filed on July 28, 2000 in connection with U.S. Serial No. 09/493,346. The above listed references 17, 18, 25, 31 and 33 were submitted to the U.S. Patent and Trademark Office in a Supplemental Information Disclosure Statement filed August 26, 2003 in connection with U.S. Serial No. 09/493,346. The above listed reference 8 was submitted to the U.S. Patent and Trademark Office in a Supplemental Information Disclosure Statement filed on June 4, 2003 in connection with U.S. Serial No. 09/493,346. Accordingly, pursuant to 37 C.F.R. §1.98(d), copies of these references are not required to be provided to the U.S. Patent and Trademark Office since they were previously cited by, or submitted to, the

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Patent Office in an application relied upon for an earlier filing date under 35 U.S.C. §120.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorneys invites the Examiner to telephone either of them at the number provided below.

Pursuant to 37 C.F.R. §1.97(b)(3), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

Mark A. Farley

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents
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Mark A. Farley 10-29-03

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Form PTO-1449		U.S. Department of Commerce Patent and Trademark Office		Atty. Docket No. 61009A /JPW/MAF/AJD		Serial No. 10/681,879									
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				Applicant(s) William C. Olson and Paul J. Maddon											
				Filing Date October 9, 2003		Art Unit									
U.S. PATENT DOCUMENTS															
Examiner Initials		Document Number							Date	Name	Class	Subclass	Filing Date If Appropriate		
	US	5	4	6	4	7	3	3	11/07/95	Bolognesi et al.					
	US	5	6	0	3	9	3	3	02/18/97	Dwyer, IV et al.					
	US	5	6	6	8	1	4	9	09/16/97	Oroszlan et al.					
	US	5	8	1	7	7	6	7	10/06/98	Allaway et al.					
FOREIGN PATENT DOCUMENTS															
		Document Number							Date	Country	Class	Subclass	Translation		
													Yes	No	
	WO	9	2	0	1	4	5	1	02/06/92	PCT					
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)															
		Allaway GP et al. (1995) Expression and characterization of CD4-IgG2, a novel heterotetramer which neutralizes primary HIV-1 isolates. AIDS Res Hum Retroviruses 11: 533-539;													
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		Kirby JM et al. (1998) Potent suppression of HIV-1 replication in humans by T-20, a peptide inhibitor of gp41-mediated virus entry", Nature Med 4: 1302-1307;	
		Laal S et al. (1994) Synergistic neutralization of human immunodeficiency virus type 1 by combinations of human monoclonal antibodies. J Virol 68: 4001-4008;	
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		Vita C et al. (1999) Rational engineering of a miniprotein that reproduces the core of the CD4 site interacting with HIV-1 envelope glycoprotein. Proc Natl Acad Sci USA 96: 13091-13096;			
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